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THE ASCA JOURNAL | JUNE/JULY 2018 | www.ascfocus.org

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Presterilizing Versus Re-Sterilizing Implants and Instruments

Considerations for ASCs, insurers, surgeons and patients **BY JOHN WELLS**



While single-use equipment is not new in health care, the kinds of instruments and related devices going the route of “one and done” are changing.

More and more surgical centers and surgeons worldwide are asking whether presterilized, single-use instruments and implant-related devices have distinct advantages over those that are repeatedly sterilized.

In orthopedics, presterilized surgical kits that supply only the implants—such as screws and plates—and accompanying instruments necessary for specific procedures are gaining traction. Orthopedic units in Scotland converted to single-use, presterilized and individually wrapped plates and screws in 2008. In its advance notice to medical practices ([http://www.sehd.scot.nhs.uk/cmof/CMO\(2006\)13.pdf](http://www.sehd.scot.nhs.uk/cmof/CMO(2006)13.pdf)), the Scottish Executive Health Department stated, “Reprocessed steel implants can cause inflammatory reactions to a much greater degree than pristine devices. . . . There are also issues of corrosion and weakening caused by repeated processing.”

Presterilized implants and instruments are already widely used in spine surgery in the US.

The typical drivers behind single-use equipment also are at work here:

- increasing financial constraints facing providers and insurers;
- reducing risk of surgical site infections (SSI); and
- greater operating room efficiencies.

Presterilized trays—that contain surgical instruments only—also are gaining popularity at ASCs. ASCs find greater efficiencies with presterilized instruments. They allow more procedures to be performed with shorter turnover



time, take less room to store, are easily received into inventory by staff, and can be supplied at similar cost to traditional implants and instruments that require processing and sterilization.

Interoperability Advantages

Seldom does a surgeon enter an operating room (OR) without a clear idea on how to treat the patient. They do, however, prefer to have the flexibility to choose the right device in those cases where, once the surgery is underway, they can fully assess the situation and change the direction of treatment if necessary.

In terms of using instrument trays that have been sterilized on-site, doctors and nurses might be presented with multiple large trays with an array of plates, screws and various other tools. Too much choice crowds case carts and back tables; plus, the potential for contamination is a concern with wrapped trays, which contain sterilized instruments wrapped with a sterilized cloth.

In contrast, presterilized instrument kits are a quarter of the size of regular trays and the surgical team uses only what is needed, cutting down on waste and minimizing contamination risk,

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while making the most of limited space in the OR.

Sterile Processing Efficiencies

Think about your facility's instrument intake procedure and its multiple steps, check-in procedures and coordination (https://www.iahcsmm.org/images/Resources/Loaner_Instrument/Position-Paper.pdf). The 24 to 48 hours many health care facilities require to receive instrument trays before a scheduled procedure promotes distraction of employees and possible missteps, not to mention the back-end cleaning, restocking and storage required caring for this inventory.

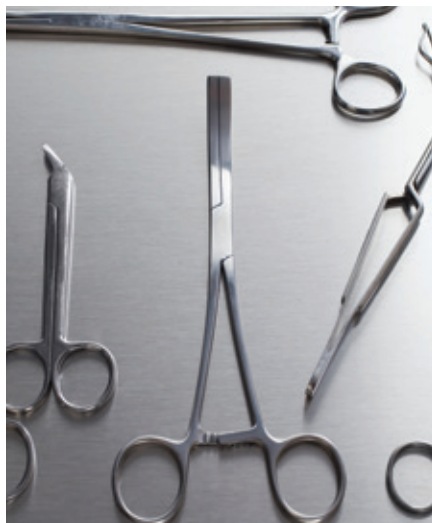
Presterilized trays streamline processing on the front and back ends:

- They take less time to check in.
- Drop-off can happen anytime, even the night before a procedure.
- They can head directly to the core and the case cart, bypassing sterilization with zero worries about possible contamination and OR delays due to a hole in the drape, moisture in the tray, an overlooked contaminated instrument or a mislabeled tray.
- They eliminate mislabeling of a wrapped tray.
- The surgical staff can see all the instruments through their clear packaging and precision content labeling. They don't have to open a tray to know exactly what they have.
- Interaction time between the health care facility and product representative is simplified and reduced.
- They relieve the financial impact for lost instruments.

Improved Inventory Access and Management

No organization wants equipment that is oversupplied and underutilized.

The idea of keeping a small emergency inventory of presterilized plates and screws for the unannounced and unplanned situation can benefit any health care facility, particularly in light of recent natural and man-made



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—John Wells
In2Bones USA

disasters. Several trays can be kept off to the side for quick access or for transport, as presterilized trays can be easily moved without fear of contamination.

Device Tracking with UDI and EHR

Ongoing federal requirements for making implantable devices adequately identifiable through the US Food and Drug Administration's (FDA) Unique Device Identification (UDI) system, and then entered into a patient's electronic health record (EHR) and insurance claims, is made easier via presterilized implants and instrument kits.

With an abundance of screws and plates of various sizes, including some that are quite small, managing what specific implants go into a patient can

make tracking and compliance difficult. Having all implants in sterile packaging with detailed labeling—including the required UDIs marked by the manufacturer—simplifies compliance and eases the data entry burden on health care staff.

Nursing Staff Efficiencies

One common complaint among health professionals is how greater data entry encroaches on their workload as clinicians. The regulatory environment around UDI compliance is complicated and sometimes a point of anxiety for health care facilities and device-makers alike. It is becoming clear that recordkeeping compliance will continue to deflect more staff time away from caring for patients. Prepackaged, single-use implants have the promise to introduce a bit more simplicity into the tracking and recording processes used with UDIs.

Gaining Traction

Of course, shifting entirely over to presterilized implants and instruments would require changes in procurement, process management, stock control, storage and contract maintenance.

Several countries have already taken these steps and are moving to a new model of presterilized small extremity implants and single-use instruments. In response, device manufacturers have created products to support this clinical push.

Considering a health care facility's need to reduce its financial burdens, minimize its infection risk and create more operational efficiencies, the switch to “one and done” makes for smart business and quality patient care and offers benefits worth the effort. ‹‹

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